DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#12

DEC 11 1990

Re: Synarel
Docket No. 90E-0156

Charles E. Van Horn, Esq.
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the patent term extension application for U.S. Patent No. 4,234,571 filed by Syntex (U.S.A.) Inc., under 35 U.S.C. 156. The patent claims the human drug product Synarel, NDA 19-886.

In the June 12, 1990 issue of the Federal Register, the Food and Drug Administration published its determination of the product's regulatory review period, as required under 35 U.S.C. 156(d)(2)(A). The notice provided that on or before December 10, 1990, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. 156 (d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to the notice has expired, and FDA has received no such petition. FDA, therefore, considers Synarel's regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Tom M. Moran, Esq.
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